TENAGA PHARMED SDN. BHD

v.

PUBLIC PROSECUTOR & OTHER APPLICATIONS

HIGH COURT, SHAH ALAM
TUAN MOHD HISHAMUDIN BIN MOHD YUNUS J.
[CRIMINAL APPEALS NO. 41-196-92, 41-198-92, 41-199-92, 41-335-92]
1 MARCH 1994

CRIMINAL LAW: Charge under s. 3(1)(b) Trade Description Act, 1972 - False description - Companies indicated as manufacturers on labels of containers of drugs only labelled and packed drugs - Whether there was misdescription - Whether offence disclosed.

CRIMINAL LAW: Section 3 Trade Description Act 1972 - Prohibition against false trade description - Exception to prohibition - Section 4(4) - Requirements and applicability - Burden of proof - Whether appellants protected by s. 4(4).

EVIDENCE: Onus of proof - False trade description - Trade Description Act 1972 s. 3 - Exception clauses - Section 4(4) - Applicability - Whether defence to prove on the balance of probabilities that exeption clause applied.

WORDS AND PHRASES: "manufacture" - Control of Drugs and Cosmetics Regulations 1984 reg. 2.

The appellants were charged before the Magistrate's Court with an offence under s. 3(1)(b) Trade Description Act 1972 (TDA) for supplying to the Kementerian Kesihatan Malaysia, bottles of drugs in respect of which false trade descriptions had been applied. The facts showed that the labels on the bottles in question described two companies viz. "Malayan Pharmaceutical Factory, Petaling Jaya" and "Hor Yan Hor Pharmaceutical Sdn Bhd", as the manufacturers of the drugs when in fact they were not the makers of the said drugs.

The appellants raised a preliminary objection in the lower Court that there was no misdescription as alleged and hence no offence disclosed, as the two companies had packed and labelled the said drugs and were therefore "manufacturers" of the drugs by virtue of the definition accorded to the word "manufacture" in regulation 2 Control of Drugs and Cosmetics Regulations 1984 (the Regulations), which definition, in effect, extended the meaning of "manufacture" of products to the activities of packing and labelling. It was further argued that even assuming that such description was false, there was still no offence committed as s. 4(4) TDA, on its true interpretation, deemed such acts of the appellants as not to be acts of false description. The Magistrate overruled the objection and hence the present appeal to the High Court.

Held:

[1] There was no evidence that the companies concerned had in fact packed the drugs into the containers and had labelled the containers. Even assuming that the appellant was in the position to adduce evidence that the companies named on the labels had packed the drugs into bottles and had labelled the bottles, the appellant was still not entitled to describe the companies as the "manufacturers" as they did not make the drugs. A company that merely packed ready made drugs into containers and thereafter labelled the containers should be described on the labels of the bottles as the person who packed and labelled the drugs. It would be a false description to describe such a company as the manufacturer notwithstanding that the definition "manufacture" in regulation 2 Control of Drugs and Cosmetics Regulations includes packing and labelling. That definition is only for the purposes of the Regulations and irrelevant for the purposes of the TDA and the appellants were not therefore entitled to rely on it.

[2] The proposition by the appellant that it was the intention of the legislature in enacting s. 4(4) TDA to permit local suppliers of such drugs to call themselves as the "manufacturer" of the drugs as long as they comply with the Sales of Drugs Act 1952 (SDA) and the Regulations is untenable. Unless the TDA and the SDA themselves are clear as to the policy consideration in enacting s. 4(4), which they are not, there is no proper basis to accede to such an interpretation. To do so would be to transgress into the realm of conjecture and speculation, if not to usurp the function of the legislature.

[3] In order for s. 4(4) TDA to be applicable it must be shown inter alia, that the SDA and the Regulations prohibited "the application of any description". This means that as a preliminary requirement, it must be shown that the SDA and the Regulations prohibited any trade

description on the labels naming the manufacturer of the drugs. There was nothing in either statutes which prohibited the application of any trade description on the container of the drugs indicating or naming the manufacturer of the drugs. On this ground alone the recourse to s. 4(4) hereof cannot succeed and must fail.

[4] Section 4(4) creates an exception to the prohibition under s. 3 TDA. The section in effect renders any application of false trade description permissible by deeming it not to be a false trade description on the satisfaction of the conditions provided therefor. This being the case by virtue of s. 105 Evidence Act 1950 the onus is on the appellants to adduce evidence to prove on the balance of probability that their acts or activities came within the exceptions. But how could the appellants satisfy this onus and raise the issue of no offence by virtue of this section when, as here, the objection was prematurely taken and hence no evidence whatsoever had been adduced by either side. Clearly, therefore, the appellants' contention in this respect must also fail.

Per Curium: With the greatest respect to those responsible for its drafting, s. 4(4) TDA appears to have been rather loosely drafted. It would be a good idea if the Legal Advisers of the relevant ministries and the Attorney General's Department re-examine this provision with the view to simplifying the drafting of the provision so that it's objective, whatever it may be, could be achieved.

[Appeals dismissed. Magistrate's ruling upheld].

Cases referred to:

Public Prosecutor v. Tan Kim Lim [1975] 1 MLJ 215 ***(foll)***

Vengadasalam v. Khor Soon Weng & Ors. [1985] 2 MLJ 449, p. 450 ***(refd)***

Thompson v. Goold & Co. [1910] AC 409, 420 ***(refd)***

Vickers, Sons and Maxim, Limited v. Evans [1910] AC 444, 445 ***(refd)***

N. Govindasamy v. Public Prosecutor [1970] 2 MLJ 49 ***(refd)***

Legislation referred to:

Control of Drugs and Cosmetics Regulations 1984, regulation 2

Evidence Act, s. 105

Sale of Drugs Act 1952

Trade Description Act 1972, ss. 3(1) (b), 4(4), 5, 18(2)

For the 1st appellant - P.C. Choong; M/s Choong & Co.

For the 2nd appellant - Jeffrey Fernandez (Koo Chin Nam with him); M/s. Koo Chin Nam & Co.

For the 3rd appellant - Harjeet Singh; M/s Shearn Delamore & Co.

For the respondent - Zainal Abidin, DPP

JUDGMENT

Mohd Hishamuddin bin Mohd Yunus J: All these four appeals were, by consent, heard together on 7 December 1993. They were heard together as a matter of convenience since the issue for the determination by the Court was common to all four cases. In dismissing the appeal, I informed the parties that in view of the issue raised I would give a written judgment

Each of the appellants was charged before the Magistrate's Court at Petaling Jaya for an offence under s. 3(1)(b) of the Trade Description Act 1972 (hereinafter referred to as the "TDA"). In appeal No. (1) (Rayuan Jenayah No. 41-197-92), the appellant, Tenaga Pharmed Sdn. Bhd. was charged as follows:

> That you on 25 September 1986 between 2.45 p.m. to 3.05 p.m. at Makmal Ubat dan Setor Kementerian Kesihatan Jalan Universiti Petaling Jaya in the District of Petaling Jaya in the State of Selangor Darul Ehsan, in the course of business did supply to Kementerian Kesihatan Malaysia 29977 ampoule Injection Promethazine Hydrochloride BP 25 mg/ml ampoule, to which a false trade description has been applied, namely, the description "Malayan Pharmaceutical Factory, Petaling Jaya" was indicated on the label of the bottles containing the said ampoules which was an indication or likely to be taken as an indication that the said company is the manufacturer when in fact the said company is not the manufacturer, and that you have thereby committed an offence under s. 3(1)(b) of the Trade Description Act 1972 and punishable under s. 18(2) of the same Act (Act 87).

In appeal No. (2) (Rayuan Jenayah No. 41-193-92), the appellant (also the same company) was charged as follows:

> That you on 17 September 1986 between 3.00 p.m to 4.00 p.m. at Makmal Ubat dan Setor Kementerian Kesihatan Jalan Universiti Petaling Jaya in the District of Petaling Jaya in the State of Selangor Darul Ehsan, in the course of business did supply to Kementerian Kesihatan Malaysia 2500 bottles @ 1000 tablets Erythromycin Stereate, to which a false trade description has been applied, namely, the description "Hor Yan Hor Pharmaceuticals Sdn. Bhd, 12, Jalan Kuala Kangsar, Ipoh, Perak" was indicated on the label of the bottles containing the said Erythromycin Stereate which

was an indication or likely to be taken as an indication that the said company is the manufacturer when in fact the said company is not the manufacturer, and that you have thereby committed an offence under s. 3(1)(b) of the Trade Description Act 1972 and punishable under s. 18(2) of the same Act (Act 87).

In appeal No. (3) (Rayuan Jenayah No. 41-199-92), the appellant, Duopharma (M) Sdn. Bhd was charged for abetting Tenaga Pharmed Sdn. Bhd. in the commission of the offence; and in appeal No. (4) (Rayuan Jenayah No. 41-335-92) the appellant, Malayan Pharmaceutical Factory Sdn. Bhd., was charged for abetting the same company, Tenaga Pharmed Sdn. Bhd., in the commission of the offence.

Section 3 (1) (b) of the Trade Description Act 1972 states:

3. Prohibition of false trade descriptions.

(1) Any person who, in the course of trade or business -

(a) ...
(b) supplies or offers to supply any goods to which a false trade description is applied, shall be guilty of an offence.

At the commencement of the trial before the learned Magistrate, learned Counsel for the appellants made a preliminary objection as to the charges. He submitted that the charges disclosed no offence. He argued that there was no misdescription in indicating on the labels of the containers (i.e. the bottles) that the companies (Malayan Pharmaceutical Factory, Petaling Jaya and Hor Yan Hor Pharmaceuticals Sdn. Bhd), named in the charges, were the manufacturers of the drugs. He contended that, although these companies did not make the drugs, nevertheless, they did pack the drugs (i.e. put the drugs in bottle containers) and label the bottles, and according to the definition under regulation 2 of the Control of Drugs and Cosmetics Regulations 1984 (P.U. (A) 223/1084) (hereinafter referred to as the "Regulations"), they were the "manufacturers" of the drugs. Regulation 2 of the Regulations defines "manufacture" as follows:

"manufacture", in relation to any product includes -

(a) the making or assembling of the product;
(b) **the enclosing or packing of the product in any container in a form suitable for administration or application, and the labelling of the the container; and**
(c) the carrying out of any process in the course of any of the foregoing activities, [Emphasis added.]

Learned Counsel further argued that, even assuming that there had been a misdescription, nevertheless, no offence had been committed by reason of s. 4(4) of the TDA. He contended that s. 4(4) of the TDA protects the appellants from prosecution. He submitted that this section deems such acts of the appellants as not to be acts of false description. Section 4(4) of the TDA reads:

4.(4) Where the application of any description is prohibited under the provisions of any of the laws specified in the First Schedule except where applied to goods which comply with the requirements of that law no such description applied in accordance with the requirements of that law shall be a false trade description, and the Minister may by order add to, delete from or modify the First Schedule.

To date, the only law specified in the First Schedule is the Parent Act of the above Regulations that is, the Sale of Drugs Act 1952 (Revised - 1989) (Act 36) (hereinafter referred to as the "SDA"). Learned Counsel submitted that, by virtue of the above s. 4(4) of the TDA, which expressly links the SDA as well as the Regulations to the TDA, the trade description as applied by the appellants to the drugs, even assuming that it was false to a material degree - since the companies named on the labels did not make the drugs (but only packed the drugs into containers and labelled the containers) - nevertheless, legally, is not a false description so long as-

(a) the drugs; and

(b) the packing of the drugs and the labelling of the containers, were in conformity with the SDA and the Regulations.

The learned Magistrate did not make any ruling as to the first contention. However, as regards the second (and alternative) contention, the learned Magistrate referred to the following clause (or rather the first limb) of s. 4(4) of the TDA -

Where the application of any description is prohibited under the provisions of any of the laws specified in the First Schedule ...

and ruled that what this clause means is that for this section to be applicable it must be ascertained, first of all, whether the SDA and the Regulations prohibit the application of the trade description to the drugs; and she came to the conclusion that the SDA and the Regulations do not prohibit the application of such trade description; and since the SDA and the Regulations do not prohibit the application of such trade description, therefore, s. 4(4) was not applicable.

Accordingly, she overruled the preliminary objection, but allowed a stay of proceeding pending appeal.

I rejected the arguments of learned Counsel. As to the first point raised, there was no evidence that the companies concerned had packed the drugs into the containers (i.e. the bottles) and had labelled the containers. Indeed, how could there be such evidence when the point was prematurely taken up by way of preliminary object before the trial. However, even assuming that the companies had carried out these activities in relation to the drugs, the appellants still could not claim that these companies were the manufacturers of the drugs. For the companies did not make the drugs. The word "manufacturer" or "manufacture" is not defined in TDA. However, Chambers Concise 20th Century Dictionary defines "manufacture" as -

> **manufacture** v.t. to make, originally by hand, now usu. by machinery and on a large scale; making of articles by physical labour or machinery, esp. on a large scale;

The Concise Oxford Dictionary defines "manufacture" as:

> **manufacture** n. Making of articles by physical labour or machinery, esp. on a large scale.

In *Public Prosecutor v. Tan Kim Lim* [1975] 1 MLJ 215 Syed Othman J. (as he then was) ruled (at page 216-217) -

> Considering the authorities, the word "manufacture" appears to me to mean in its general sense the making by labour or machine of an object or various objects into another object of a different character. Thus if a slab of granite is carved into a grindstone, a piece of wood is made into a piece of furniture, or a lump of earth into brick, it is manufacture. Similarly, if transistors, condensers, resistors and pieces of wire are put together into a box so as to convert them into a radio or a television set, or if pieces of shaped iron sheets, rubber glass, fabrics and other materials are assembled and turned into a vehicle it is 'manufacture'.

On the basis of the above authorities, it is clear that even assuming that the appellants were in a position to adduce evidence that the companies named on the labels had packed the drugs into bottles and had labelled the bottles, they were not entitled to describe those companies as the "manufacturers" of the drugs: the manufacturers of the drugs were the companies (whoever they might be) that made the drugs. A company that merely packed the ready made drugs into containers and thereafter labelled the containers should be described on the label of the bottles as the person who packed and labelled the drugs. It would be a false description to describe such a company as the "manufacturer". It makes no difference that the definition of "manufacture" in the Regulations includes packing and labelling. It is my view that the appellants were not entitled to rely on that definition for the purpose of the TDA that definition is only for the purposes of the Regulations and is irrelevant for the purposes of the TDA.

On the second (alternative) argument, at the hearing of these appeals, it was further argued on behalf of the appellants that it was the intention of the legislature in enacting s. 4(4) of the TDA to permit local suppliers of such drugs, who comply with the SDA and the Regulations, to call themselves as the "manufacturer" of the drugs, even though they are not the makers of the drugs (but merely packed and labelled) since (to quote Encik Fernandez) "Parliament intended to cultivate the phar-maceutical industry in this country and appreciates the fact that we are a developing country and that, at the present moment, the local companies have neither the resources nor attained the standard of technology so as to be in a position to make such drugs."

Learned Counsel tried hard to persuade me to accept his interpretation of s. 4(4) of the TDA and his understanding of the rationale of that provision. With respect, I am not prepared to do so. Unless the TDA and the SDA themselves are clear as to the policy consideration in enacting s. 4(4) and with all humility I would say that it is wholly unclear - I am not prepared to accept the interpretation and the rationale as proposed by learned Counsel; for to do so would be to transgress into the realm of conjecture and

speculation, if not to usurp the function of the legislature. I am reminded of what Abdoolcader SCJ said in *Vengadasalam v. Khor Soon Weng & Ors.* [1985] 2 MLJ 449, at p. 450:

> It would appear to us that the learned Judge has in fact by his determination on this matter purported to inject policy considerations in his construction of the requisite provisions of the Act in the face of its textual connotation. This would be taking statutory construction beyond its permissible limits, and we would refer to what has been said in this regard in *Merdeka University Berhad v. Government of Malaysia* (at page 358) [1981] 2 MLJ 356.

In this regard, I also wish to advert to the judgment of the House of Lords in *Thompson v. Goold & Co.* [1910] AC 409, 420 where Lord Mersey said (at page 420):

> It is a strong thing to read into an Act of Parliament words which are not there, and in the absence of a clear necessity it is a wrong thing to do.

Even more pertinent perhaps would be the salutary reminder of Lord Loreborn L.C., in *Vickers, Sons and Maxim, Limited v. Evans* [1910] AC 444, 445 when he said (at page 445)

> My Lords, this appeal may serve to remind us of a truth sometimes forgotten, that this House sitting judicially does not sit for the purpose of hearing appeals against Acts of Parliament, or of providing by judicial construction what ought to be in an Act, but simply construing what the Act says. We are considering here not what the Act ought to have said, but what it does say; ... The appellant's contention involves reading words into a clause. The clause does not contain them; and we are not entitled to read words into an Act of Parliament unless clear reason for it is to be found within the four comers of the Act itself.

In rejecting learned Counsel's argument, I must, however, confess that I encounter great difficulty in interpreting s. 4(4). It is a vague provision. Attempting to interpret and to ascertain the meaning of such phrases as "the application of any description", "goods which comply with the requirements of that law, and "description applied in accordance with the requirements of that law" is an exasperating experience. Indeed, it is a near impossible task. With the greatest respect to those responsible for its drafting, the provision appears to me to have been rather loosely drafted. I believe - if I may be permitted to suggest - that it would be a good idea if the learned Deputy Public Prosecutor could consider bringing to the attention of the Legal Advisers of the relevant Ministries and the Attorney General's Department of the need to reexamine the provision of s. 4(4) of the TDA with the view to simplifying the drafting of this provision so that the objective of the provision, whatever it may be, could be achieved.

However, be that as it may, there is a pertinent issue which should have been addressed to (but was not) by the parties in their submissions before the learned Magistrate. This issue was also glossed over during the arguments at the hearing of these appeals. The issue is this. As a matter of law, was it the duty of the prosecution, in order to prove a *prima facie* case against the defendants, to prove that s. 4(4) was not applicable? Or was the legal burden placed on the defence to prove that that provision was applicable? ln my view - and it is important to appreciate this fact - s. 4(4) creates an exception to the prohibition under s. 3 of the TDA. Section 4(4) renders any application of false ("false in the sense as stipulated by s. 5 of the TDA) trade description permissible by deeming it not to be a false trade description provided certain conditions, as stipulated under that section, are satisfied. This being the case, by virtue of s. 105 of the Evidence Act, the onus was on the defence to adduce evidence to prove (and not for the prosecution to prove otherwise) that the act or activity of the appellants came within the exception. And as to the standard of prove, it was incumbent upon the defence to prove on a balance of probability (*M Govindasamy v. Public Prosecutor* [1970] 2 MLJ 49).

Now, if the burden was on the defence to adduce evidence to prove on a balance of probability that the act or activity of the appellants fell squarely within the exception as provided for by s. 4(4), I am rather perplexed as to how it was possible for the defence to have raised such an issue (that the charges disclosed no offence by virtue of s. 4(4) of the TDA) as a preliminary objection before any evidence had been adduced by either side! Normally, in such a case as the present, such a point would be taken up by the defence only during the submission after the defence has closed its case; and, perhaps, in exceptional cases, the point may also be taken up by the defence during the submission of no case to answer at the close of the case for the prosecution, if the defence is of the view that the

evidence emerging from the testimonies of the prosecution's witnesses, during cross examination, discloses that the case falls under an exception which exonerates the defendant.

At the hearing of these appeals, when I posed to learned Counsel the issue of burden of proof, the brief and simple reply was that, for the purpose of the preliminary objection, there was no necessity for any evidence to be adduced by either party since the prosecuting officer at the hearing before the learned Magistrate had conceded that there was no misdescription under the Regulations and that the appellants had complied with the requirements under the Regulations. I quote what learned Counsel, Encik Jeffrey Fernandez, had actually said:

> Under regulation 2 [of the Regulations], the word "manufacture" is defined. It is clear that packaging and labelling fall within the definition of "manufacture". Therefore, there had been no misdescription under these Regulations of 1984. The prosecuting officer conceded on this point. See page 40 of the Appeal Record at paragraph 4 [of the written submission of the prosecuting officer]. The prosecution conceded that the subject matter of this case complied with the requirements under the Regulations of 1984.

Now, paragraph 4 of the written submissions of the Prosecuting Officer reads:

> 4. Adalah diakui bahawa pelabelan terhadap barangan yang menjadi "subject matter" di dalam kes ini dibuat sebagai mematuhi kehendak-kehendak di dalam Peraturan-Peraturan Kawalan Dadah dan Kosmetik 1984. Walau bagaimanapun, isu-isu berikut turut juga menjadi persoalan:
>
> (a) sama ada defendan sendiri atau syarikat yang telah dicatitkan sebagai pembuat pada label barangan di dalam kes ini boleh dipanggil "pembuat" ("manufacturer") berdasarkan definasi di dalam Peraturan-Peraturan tersebut;
> (b) sama ada di dalam melabelkan barang-barang berkenaan telah berlaku salah perihal (misdescription) oleh defendan;
> (c) sama ada perbuatan salah perihal tersebut jika ada) dilarang oleh atau menjadi suatu kesalahan di bawah Akta Jualan Dadah 199 serta peraturan-peraturan yang dibuat di bawahnya.

It is to be noted that what was conceded by the prosecuting officer was only that the "labelling" of the drugs was in accordance with the Regulations. Therefore, it is clear that learned Counsel, by claiming that the prosecution conceded that the subject matter of this case complies with the requirements under the Regulations, had overstretched the concession made by the prosecution. Nowhere in his written submission did the prosecuting officer state that the drugs (ie the "subject matter" of the case) comply with the requirements of the Regulations. He merely stated that the labelling was in compliance with the Regulations. It follows therefore that, contrary to the claim made by Encik Fernandez, there had been no unequivocal and complete concession made by the prosecuting officer to the defence so as to satisfy the Court that all the necessary requirements under s. 4(4) of the TDA had been met.

What are the necessary requirements of s. 4(4)? In my opinion, in order to 'comply with the requirements of s. 4(4), the following three limbs of the provision must be satisfied:

> First, Where the application of any description is prohibited under the provisions of any of the laws specified in the First Schedule ...
>
> Secondly, ... except where applied to goods which comply with the requirements of that law ...
>
> Thirdly, ... such description applied in accordance with the requirements of that law ...

Bearing in mind what I have lamented above regarding the difficulty in interpreting s. 4(4), what all this means, in the context of the charges, is that, the onus was on the defence to show:

Firstly, that such a trade description as applied to the drugs in question, that is to say, naming the manufacturer of the drug, as what the defendants had done in the present case, was prohibited by the SDA except in cases where the trade description was applied to drugs which complied with the requirements of the SDA;

Secondly, that the drugs in question did comply with the requirements of the SDA; and

Thirdly, that the trade description, as applied to the drugs in the present case (i.e. naming the manufacturer) by the defendants, was applied in accordance with the requirements of the SDA.

Since the prosecution did not in clear terms concede that all the requirements as enumerated above were satisfied, I am unable to accept learned Counsel's contention that there was no necessity for the defence to adduce any evidence

in order to rely on the exception provided for by s. 4(4).

Now, it will be recalled that the learned Counsel, in his submission, had suggested that all that was necessary, in order to seek the protection of s. 4(4), was for the defence merely to show that the appellants had satisfied the requirements that

(a) the drugs; and

(b) the packing of the drugs and the labelling of the containers,

were in conformity with the SDA and the Regulations.

With respect, such a suggestion is too simplistic a view of the interpretation of s. 4(4). To adopt that approach is to gloss over the first limb of that provision. I am of the view that in order for s. 4(4) to be applicable, first of all the Court must be satisfied that the SDA and the Regulations prohibit "the application of and description". This means that, as a preliminary requirement, the Court must be satisfied that the SDA and the Regulations prohibit any trade description on the labels naming the manufacturer of the drugs. This must be the interpretation to be given, for s. 4(4) of the TDA must be read with s. 4(1) of the same Act which defines "trade description" as follows:

4. **Trade description.**

(1) A trade description is an indication, direct or indirect, and by whatever means given, of any of the following matters with respect to any goods or parts of goods, that is to say -

(a) ...
(b) ...
...
...
(j) person by whom manufactured, produced, processed or reconditioned;

In other words, in the light of s. 4(1), the words "any description" in s. 4(4) must be interpreted to mean any trade description of the "person by whom [the goods were] manufactured".

I have scrutinised the SDA and the Regulations and I find nothing in the SDA or the Regulations which prohibits the application of any trade description on the container of the drugs indicating or naming the manufacturer of the drugs. If this first requirement itself could not be satisfied, then there is nothing further to inquire into.

Therefore, in conclusion, I must hold that the preliminary objection raised before the learned Magistrate was misconceived and premature, and that the learned Magistrate was right in law in overruling the preliminary objection.